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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,043	10/04/2000	Erling Sundrehagen	REF/Sundrehagen/127	4723

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/679,043	SUNDREHAGEN ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-54,58-70 and 73-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-54, 58-70 and 73-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election Restriction

1. Applicants response to the Office Action mailed 1/9/06 is acknowledged (Paper filed 7/10/06). Claim 50 was modified. Claims 55-57, and 71-72 have been canceled without prejudice or disclaimer. New claims 73-75 have been added. Currently claims 50-54, 58-70, and 73-75 are pending and under consideration.

2. Rejections and/or objections of record not reiterated herein have been withdrawn.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Double Patenting

3. Double patenting obviousness-type rejection:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 50-54, 58-, and 73-75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Application No. 10/897,433. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to holo-TC11 analysis procedures. This invention is encompassed within Application #10/897,433. This is a provisional obvious-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

5. Applicants request that this rejection be held in abeyance until there is an indication of allowable subject matter. Accordingly the rejection is maintained.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 50-54, 58-70, and 73-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth an assay method employing cobalamin for selectively binding the apo-forms of TC II and haptocorrin (HC) in a sample and therefore the written description is not commensurate in scope with the claims drawn to the utility of any fragment thereof.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117).

The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of cobalamin, the skilled artisan cannot envision the detailed structure of the encompassed binding fragments thereof and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of a compound/seq.id/etc. by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules, usually defined by a sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description ...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

However, no disclosure, beyond cobalamin is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only cobalamin, but not any fragment thereof would meet the full breadth of the claims as required by the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 50-52, 65-68, 71 and 73-74 are rejected under 35 U.S.C. 103(a) as being obvious over Herbert (US Patent #4,680,273) in view of J. Van Kapel et al. (Clinica Chimica Acta, 172, 1988, 297-310) and further in view of Frater-Schroeder et al. (Analytical Biochemistry, 1982, Vol.124, No.1, pages 92-101, Abstract Only).

Hebert discloses various assays to measure transcobalamin II bound cobalamin. See column 3 – column 6. In one instance applicable assays wherein a body sample is contacted with labeled vitamin B12, therein allowing the cobalamin in the sample and labeled cobalamin to compete for binding to a binding ligand.

The amount of bound verse free vitamin B_{12} or cobalamin was used to identify the amount of vitamin B_{12} or cobalamin present in the sample. See column 1 lines 12-41. The detection of vitamin B_{12} or cobalamin is subsequently employed to determine the vitamin B_{12} carried by transcobalamin II (holo-TC II) in the sample (holo-TCII). This reads on Applicant's claims directed to the measurement of holo-TCII via cobalamin.

Although Herbert does not specifically recite that cobalamin selectively binds apo-forms of TCII and haptocorrin, it is noted that the use of cobalamin would necessitate the same binding characteristics noted by Applicant.

Specifically, Herbert teaches a method of determining the amount of vitamin B12 or cobalamin in a sample. Holo-TCII or TCII containing bound vitamin Bl2 is taught in column 2 lines 29-31. The sample can be a cell free sample, like serum (blood extracted fluid free from solid elements) and can detect Vitamin B12 carried by TCII (holo-TCII) at levels as low as 15pg/ml. Therein reading on applicants 9pM or 9pg/l – claim 52. See column 6 lines 37-47 for example. In table I in column 7 lines 30-49 at least a three fold increase over deficient patients is exhibited as required by claim 51. The assay for vitamin B_{12} is accomplished by using a binder specific for cobalamins (column 5 lines 10-15). In an immunoassay the binder can be a monoclonal or polyclonal antibody, a tracer is also used which can be vitamin B_{12} or an appropriate analog that is labeled with a detectable marker (column 5 lines 16-30).

The binder can be in either supported or unsupported form, and in the instances where the binder is supported, it can be supported by a solid support and the bound free fractions may be separated without the use of a separating agent, while if the binder is unsupported, then the bound free fractions can be separated by using a separating agent (column 5 lines 33-42).

The cobalamin may be determined by providing a blood sample, which contains essentially only TCII. (column 3 lines 3-6). Separation may be conducted via precipitation of TCII, although other methods for separating TCII from a sample are applicable (column 3 lines 40-46).

In one embodiment, TCll can be separated from a sample using selective antibodies (column 3 lines 54-55) where the antibody can be coupled to a solid support to more easily separate TCII (column 3 lines 63-64). At pH=6, TCII binds to sephadex while the other transcobalamin proteins do not (column3 line 65). Once the TCII-vitamin B12 solution is obtained, the resulting solution may be subjected an assay for vitamin B12 where radioassay for vitamin B12 includes the removal of vitamin B12 from TCII complex, for example by heating or the use of hydrochloric acid at pH=2 to destroy the TCII and removal of the B12 (column 4 lines 15-20). Vitamin Bl2 dissociates from TCII when both the ionic strength and pH are low (column 4 lines 35-37). Thus cobalamin can be selectively freed from TCII (column 4 lines 25-26). Binding of additionally haptocorrins are also taught, along with methods of separation and detection (column 3-4).

Herbert differs from the instant invention in not specifically teach the use of a specific binding ligand for holo-TCII.

However, J. Van Kapel et al. disclose an assay procedure to for the quantification of cobalamin-saturated (holo TCII) transcobalamin II and unsaturated (apo) transcobalamin II in human plasma. Heparin-conjugated sepharose beads are employed to bind the complex of interest. See abstract. In the assay, radioactive cobalamin (CN[57Co]Cbl is mixed with the plasma sample and heparin-sepharose. The sepharose-bound radioactivity was measured and the apo-TCII concentration was expressed in pmol/l plasma. See page 301 – middle section. The samples were also measured for holo-TCII concentrations. See page 305 2nd paragraph. The assays are taught to be reliable for the measurement of Cbl-unsaturated (apo) transcoalamin II and saturated (holo) transcobalamin II.

These assays are further taught to be easily fitted in existing techniques for the measurement of total cobalamin and total cobalamin binding capacity. The measurement of saturated (holo-TCII) and unsaturated cobalamin (apo-TCII)-binding proteins are taught to be important in various disease states. See page 298.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ specific binding ligands to apo TCII and/or detect apo TCII separate from holo TCII as taught by J. Van Kapel et al. in the method of Herbet because J. Van Kapel et al. taught that apo TCII and holo TCII were each useful in identify various disease states. See page 298.

Herbert in view of J. Van Kapel et al. differ from the instant invention in not specifically teaching the pre-binding of apo-TCII by immobilized cobalamin.

However, Frater-Schroeder-Schroeder et al. disclose that mean holo-TC II is measured by the subtraction of apo-TC II from total TC II. See abstract.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to eliminate apo-forms of TC II with an immobilize cobalamin as exemplified in the method of Herbet in view of J. Van Kapel et al. because Frater-Schroeder et al. taught that Total TC measurements included both holo-TC II and apo-TC II measurements. Frater-Schroeder et al. further taught that holo-TC II was measured by the subtraction of apo-TC II from total TC II.

One of ordinary skill in the art would have been motivated to eliminate apo-TC II from the measurement of Total TC in order to receive an accurate and precise determination of holo-TC II levels in a sample.

II. Claims 62-64 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbert (US Patent #4,680,273) in view of J. Van Kapel et al. (Clinica Chimica Acta, 172, 1988, 297-310) and further in view of Frater-Schroeder et al. (Analytical Biochemistry, 1982, Vol.124, No.1, pages 92-101, Abstract Only) as applied to claims 50-52, 65-68, 71 and 73-74 above, and further in view of Hoyle et al. (US Patent #5,451,508).

Please see Herbert in view of J. Van Kapel et al. and further in view of Frater-Schroeder et al. as set forth above.

Herbert in view of J. Van Kapel et al. and further in view of Frater-Schroeder et al. differ from the instant invention in not specifically teaching various assay configurations including a two receptors/ligands to vitamin B12 (immobilized cobalamin competes with labeled ligand and sample ligand).

However, Hoyle et al. teach a method of assaying vitamin B12 based on competitive binding, which employs a labeled reactant (ligand) as well as the ligand present in the sample of interest. See abstract and column 2 lines 35-63.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use at least two receptors to vitamin B12 or cobalamin as taught by Hoyle et al. in the assay for bound cobalamin of Herbert in view of J. Van Kapel et al. and further in view of Frater-Schroeder et al. because Hoyle et al. taught that this procedure eliminated false positives, was rapid, and useful in clinical settings. See column 1 line 63 through column 2 line 27.

III. Claims 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbert (US Patent #4,680,273) in view of J. Van Kapel et al. (Clinica Chimica Acta, 172, 1988, 297-310) and further in view of Frater-Schroeder et al. (Analytical Biochemistry, 1982, Vol.124, No.1, pages 92-101, Abstract Only) as applied to claims 50-52, 65-68, 71 and 73-74 above, and further in view of McLean et al. (Blood, Vol.89, No.1, January 1, 1997, pages 235-242).

Please see Herbert in view of J. Van Kapel et al. and further in view of Frater-Schroeder et al. as set forth above.

Herbert in view of J. Van Kapel et al. and further in view of Frater-Schroeder et al. do not teach the methods employing recombinant holo-TCII.

However, McLean et al. disclose plasma protein TCII binding to cobalamin and the delivery of cobalamin to cells. The deficiency of cobalamin or Cbl in cells can lead to anemia. An in vitro system employing recombinant human holo-TCII was established to measure the delivery of Cbl to cells by TCII. See abstract. The use of recombinant holo-TCII exhibited a dose-dependent enhancement of the viability and proliferation of the cells. See page 237 2nd column.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use recombinant holo-TCII as taught by McLean et al. in the method of Herbert in view of J. Van Kapel et al. and further in view of Frater-Schroeder et al. because McLean et al. taught that recombinant holo-TCII not only efficiently bound cobalamin but could be used to assess cell delivery of cobalamin. The evaluation of cobalamin delivery to cells is an effective in assessing anemia. See abstract and page 237-2nd column.

IV. Claims 58-59 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbert (US Patent #4,680,273) in view of J. Van Kapel et al. (Clinica Chimica Acta, 172, 1988, 297-310) and further in view of Frater-Schroeder et al. (Analytical Biochemistry, 1982, Vol.124, No.1, pages 92-101, Abstract Only) as applied to claims 50-52, 65-68, 71 and 73-74 above, and further in view of Hoyle et al. (US Patent #5,451,508).

Please see Herbert in view of J. Van Kapel et al. and further in view of Frater-Schroeder et al. as set forth above.

Herbert in view of J. Van Kapel et al. and further in view of Frater-Schroeder et al. do not teach the specific affinity constants and antibody specificity as recited in claims 58-59 and 60-61. However, Hoyle et al employ specific monoclonal antibodies having high affinity constants use in all immunoassays since they are known in the art to increase sensitivity of the immunoassay.

Hoyle et al. teach the use of monoclonal antibodies with affinity constants of at least 5 x 10^9 Mol^{-1}, and most preferably 5 x10^{10}. Figure 2 shows more sensitive antigen determination was achieved with monoclonal antibodies. The affinity properties as recited by the claims are conventional affinities for monoclonal antibodies. Thus, one of skill in the art would desire a high affinity antibody to increase sensitivity of the assay.

Response to Arguments

Applicant's arguments have been carefully considered and were found persuasive. Applicant contends that previously cited references did not teach the combination of apo-binding pretreatment (subtraction) with the assessment of TC II to provide a measurement for holo-TCII.

Accordingly, the reference to Frater-Schroeder et al. (Analytical Biochemistry, 1982, Vol.124, No.1, pages 92-101, Abstract Only) has been added to the rejections to make obvious the importance of apo- TC II elimination in total TC measurements in order to evaluate holo-TC II. While a deficiency in a reference may overcome a rejection under 35 USC 103, a reference is not overcome by pointing out that a reference lacks a teaching for which other references are relied. In re Lyons, 364 F.2d 1005, 150 USPQ 741, 746 (CCPA 1966).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant further argues that the cited reference to J. Van Kapel et al. (Clinica Chimica Acta, 172, 1988, 297-310) provides for no selective binding of apo-TC II over holo-TC. This argument was carefully considered but not found persuasive because J. Van Kapel et al. were cited in combination with Herbert (US Patent #4,680,273) and Herbert teaches the used of cobalamin to bind TC. Although Herbert does not specifically recite that cobalamin selectively binds apo-forms of TCII and haptocorrin, it is noted that the use of cobalamin would necessitate the same binding characteristics noted by Applicant. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Applicant contends that the references do not teach separate binding, however the abstract of Frater-Schroeder et al. discloses solid-phase immunoassays for vitamin B12(cobalamin) and transcobalamin II. The mean holo-TC measurement is estimated by subtracting apo-TC from total TC II measurements.

The reference to Jacobsen et al. (Blood, Vol.55, No.1, January 1980, pages 160-163) has been removed form the instant rejections. Accordingly arguments against Jacobsen et al. are MOOT.

Applicant's arguments that the further rejections under 35 USC 103(a) do not overcome the deficiencies of the primary references against Herbert (US Patent #4,680,273) in view of J. Van Kapel et al. (Clinica Chimica Acta, 172, 1988, 297-310) and further in view of Frater-Schroeder et al. (Analytical Biochemistry, 1982, Vol.124, No.1, pages 92-101, Abstract Only). The primary references have been addressed a priori. Therefore the rejections are maintained.

8. For reasons aforementioned, no claims are allowed.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

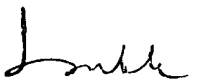
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Remsen 3C-59
571-272-0816
9/25/06



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